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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,570	07/03/2001	Valerie L. Gerlach	15966-776 CIP (CURA-276 C	2892

30623 7590 05/05/2004

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EXAMINER	
BRANNOCK, MICHAEL T	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceed...

Office Action Summary	Application No.	Applicant(s)	
	09/898,570	GERLACH ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-82 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-82 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 29, 32, 41-44, 69, 72, 75 (as the claim relates to polypeptides) drawn to polypeptides, classified in class 530, subclass 350.

II. Claims 5-14, 30, 33, 45-54, 70-73, 75 (as the claim relates to polynucleotides) drawn to polynucleotides and host cells, classified in class 536, subclass 23.5.

III. Claims 15-17, 31, 34, 55-57, 71, 74, 75 (as the claim relates to antibodies) drawn to antibodies, classified in class 530, subclass 388.22.

IV. Claims 18, 37, 58, 78, drawn to methods of detecting a polypeptide, classified in class 436, subclass 501.

V. Claims 19, 38, 59, 79, drawn to methods of detecting a polynucleotide , classified in class 435, subclass 6.

VI. Claims 20-22, 35, 36, 60-62, 76-77, drawn to methods of binding to an modulating the activity of a polypeptide, classified in class 435, subclass 7.21.

VII. Claims 23-28, 39, 40, 63-68, 80-82, drawn to methods of treatment, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is

deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-III are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group I can be prepared by processes which are materially different from recombinant DNA expression of Group II, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group II can be used other than to make the protein of Group I, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibody of Group III can be used to obtain the DNA of Group II, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups IV – VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group IV requires a method of detecting a protein with an antibody, which is not required by any of the other groups. Group V requires a method for detecting a polynucleotide, which is a fundamentally different process than that of group IV and is not required by any of the other groups. Group VI requires methods of identifying binding partners of a polypeptide and/or modulating its activity, which is not

required by any of the other groups. Group VII requires methods of treatment, which is not required of any of the other groups.

The polypeptides of Group I are related to the methods of Groups IV, VI, VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group I are patentably distinct from each of the methods of Groups IV, VI, VII because the polypeptides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV, VI, VII are materially and functionally distinct from the others. Furthermore, the polypeptides of Group I and the method of Group V are patentably distinct because one is not required for the use of the other.

The polynucleotides of Group II are related to the methods of Groups V-VII as product and process of use. In the instant case the polynucleotides of are patentably distinct from each of the methods of Groups V-VII because the polynucleotides can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V-VII are materially and functionally distinct from the others. Furthermore, the polynucleotides of Group II and the methods of Group IV are patentably distinct because one is not required for the use of the other.

The antibodies of Group III are related to the methods of Groups IV, VI, VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies are patentably distinct from each of the methods of Groups IV, VI, VII because the antibodies can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups IV, VI, VII are materially and functionally distinct from the others. Furthermore, the antibodies of Group III and the method of Group V are patentably distinct because one is not required for the use of the other.

Claims 1-82 are generic to a plurality of disclosed patentably distinct species comprising polypeptides of 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, and polynucleotide encoding same. Each polypeptide and each polynucleotide are distinct and divergent molecules, the use of one not being required for the of any other. Furthermore, a search of one could not be relied upon, solely, to provide art that is anticipatory or that might render obvious any other, and to search more than one species in a single application would be unduly burdensome. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (571) 272-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

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April 20, 2004